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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/402,713	06/13/00	BUSSEMAKERS	M 1619.0020001

HM22/0627  
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EXAMINER

WELLS, M  
ART UNIT PAPER NUMBER

1642  
DATE MAILED:

*13*  
06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/402,713

Applicant(s)

BUSSEMAKERS, MARION J. G.

Examiner

Matthew O. Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5, and 11-13, drawn to the special technical feature of a nucleic acid encoding a polypeptide comprising the amino acid sequence as SEQ ID NO: 2.

Group II, claims 1, 2, 5, and 11-13, drawn to the special technical feature of a nucleic acid encoding a polypeptide comprising the amino acid sequence as SEQ ID NO: 7.

Group III, claims 1, 2, 6, and 11-13, drawn to the special technical feature of a nucleic acid comprising the sequence encoding a polypeptide comprising the amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97.

Group IV, claims 1, 2, 7, and 11-13, drawn to the special technical feature of a nucleic acid comprising the sequence encoding a polypeptide comprising the amino acid sequence encoded

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by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521.

Group V, claims 1, 3, 4, and 1-13, drawn to the special technical feature of a nucleic acid comprising the nucleotide sequence set forth as SEQ ID NO: 1.

Group VI, claims 1, 4, and 11-13, drawn to the special technical feature of a nucleic acid comprising the nucleotide sequence set forth as SEQ ID NO: 3.

Group VII, claims 1, 4, and 11-13, drawn to the special technical feature of a nucleic acid comprising the nucleotide sequence set forth as SEQ ID NO: 4.

Group VIII, claims 1, 3, 4, 11-13, drawn to the special technical feature of a nucleic acid comprising the nucleotide sequence set forth as SEQ ID NO: 6.

Group IX, claims 1, 8, 10-13, drawn to the special technical feature of a nucleic acid encoding PCA3, wherein said nucleic acid molecule is or is complementary to a nucleotide sequence consisting of at least 10 consecutive nucleotides from PCA3 exon 1,2, 3, 4a, 4b, 4c, or 4d.

Group X, claim(s) 9, drawn to the special technical feature of detecting PCA3 nucleic acid.

Group XI, claim(s) 14, drawn to the special technical feature of a transgenic organism.

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Group XII, claim(s) 15-16, drawn to the special technical feature of a polypeptide comprising an amino acid sequence at least 90% identical to a sequence comprising the amino acid sequence in SEQ ID NO: 2.

Group XIII, claim(s) 15-16, drawn to the special technical feature of a polypeptide comprising an amino acid sequence at least 90% identical to a sequence comprising the amino acid sequence in SEQ ID NO: 7.

Group XIV, claim(s) 15-16, drawn to the special technical feature of a polypeptide comprising an amino acid sequence at least 90% identical to a sequence comprising the amino acid sequence encoded by the cDNA clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97.

Group XV, claim(s) 15-16, drawn to the special technical feature of a polypeptide comprising an amino acid sequence at least 90% identical to a sequence comprising the amino acid sequence encoded by the cDNA clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521.

Group XVI, claim(s) 17 and 19-20, drawn to the special technical feature of an antibody which binds a PCA3 polypeptide.

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Group XVII, claim(s) 18, drawn to the special technical feature of detecting PCA3 using an antibody to PCA3.

Group XVIII, claim(s) 21, drawn to the special technical feature of a method of treating prostate cancer by administering antibody to a mammal.

Group XIX, claim(s) 22, drawn to the special technical feature of a method of treating prostate cancer by administering antisense PCA3 nucleic acid.

Group XX, claim(s) 23, in part, drawn to the special technical feature of diagnosing prostate cancer by determining the amount of PCA3 RNA.

Group XXI, claim(s) 23, in part, drawn to the special technical feature of diagnosing prostate cancer by determining the amount of PCA3 protein.

The inventions listed as Groups I-XXI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XXI appears to be that they all relate to a gene designated in the application PCA3, which is related to prostate cancer. However, Bussemakers M J G et al.: "DD3: A new prostate specific marker, overexpressed in prostatic tumors.", 87<sup>th</sup> Annual Meeting

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of the American Association of Cancer Research, Washington, DC, USA, April 20-24, 1996, or Proceedings of the American Association for Cancer Research Annual Meeting 37 (0). 1996, 515, as listed on PCT form 409 (D1 and D2), teaches the gene DD3 (PCA3 is also named DD3), which is related to prostate cancer, as was set forth in the PCT search report, CA98/00346, 25 Aug 1998. Therefore, the technical feature linking the inventions of groups I-XXI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The nucleic acids, as set forth as SEQ ID NOs: 1, 3, 4, and 6, have different structures and encode different polypeptides. The polypeptides as set forth in SEQ ID NOs: 2, and 7, are structurally distinct and have different immunological properties. Absent some evidence to the contrary, the polynucleotide clones contained in deposits CBS 682.97 and 1000521, are structurally distinct from each other and from the nucleic acids of SEQ ID NOs: 1, 3, 4, and 6.

As set forth in the groupings above, the technical features of groups I-XXI each have a unique special technical feature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Wells whose telephone number is 703-308-4521.

The examiner can normally be reached on M-F (7:00-4:30), every other Monday off.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Matthew Wells

June 12, 2001

*Brenda Brumback*  
**BRENDA BRUMBACK**  
**PATENT EXAMINER**